



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,521	06/15/2006	Jean-Francois Bonfanti	TIP-0063USPCT	7548
27777	7590	10/12/2007	EXAMINER	
PHILIP S. JOHNSON JOHNSON & JOHNSON ONE JOHNSON & JOHNSON PLAZA NEW BRUNSWICK, NJ 08933-7003			STOCKTON, LAURA LYNNE	
			ART UNIT	PAPER NUMBER
			1626	
			MAIL DATE	DELIVERY MODE
			10/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<p align="center">Office Action Summary</p>	<p>Application No.</p> <p>10/596,521</p>	<p>Applicant(s)</p> <p>BONFANTI ET AL.</p>	
	<p>Examiner</p> <p>Laura L. Stockton, Ph.D.</p>	<p>Art Unit</p> <p>1626</p>	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 and 33-39 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 12, 21-24 and 33-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8-11, 13-20 and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>May 4, 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1626

DETAILED ACTION

Claims 1-30 and 33-39 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group II {Claims 1-3, 8-11, 13-20 and 25-30 - drawn to products of the formula wherein Q is R^a and R¹ is a monocyclic heterocycle} in the reply filed on August 1, 2007 is acknowledged. The traversal is on the ground(s) that:

(1) the assertion in the Restriction that Groups I-XI are "not so linked as to form a single general inventive concept under PCT Rule 13.1" lacks the required support since the burden is on the Examiner to cite appropriate prior art to clearly show that the defined Groups clearly have distinct status in the art; and (2) the cost of filing numerous divisionals is an undue burden on Applicant. This is not found persuasive because the claims lack unity of invention

Art Unit: 1626

as stated in the Restriction Requirement. Relevant and appropriate prior art was cited in the Restriction Requirement. See page 5, first full paragraph, wherein a compound of CA Registry No. 934-32-7 is referenced to show that the core is known in the art. Further, it would impose an undue burden on the Examiner and the Patent Office's resources if the instant application were unrestricted.

The requirement is still deemed proper and is therefore made FINAL.

Subject matter not embraced by elected Group II and Claims 4-7, 12, 21-24 and 33-39 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 1, 2007.

Art Unit: 1626

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statement filed on May 4, 2007.

Claim Objections

Claim 29 is objected to for being substantial duplicates of claim 1. When two claims in an application are duplicates, or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to reject the other as being a

Art Unit: 1626

substantial duplicate of the allowed claim. M.P.E.P.

706.03(k).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 8-11, 13-20 and 25-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, under the definition of R^{6a}, "or a heterocycle" should be changed to "and a heterocycle" for proper Markush language format.

Art Unit: 1626

In claim 1, under the definition of R^{8a} , an "or" is needed before the last substituent listed.

In claim 1, under the definition of R^{8b} , an "or" is needed before the last substituent listed.

In claim 1, under the definition of Het, an "or" is needed before the last substituent listed.

In claim 2, R^{8c} representing hydrogen lacks antecedent basis from claim 1.

In claim 3, R^{8c} representing hydrogen lacks antecedent basis from claim 1.

In claims 4 and 5, since variable t is not found in independent claim 1 and not defined in dependent claim 4 or dependent claim 5, the definition of the t variable has not been defined.

In claim 13, an "and" is needed before "C₁-alkyloxy" (end of line 3 of claim).

Art Unit: 1626

In claim 14, R^{3a} lacks antecedent basis from claim 1.

In claim 15, R^{3a} lacks antecedent basis from claim 1.

In claim 16, R^{3a} lacks antecedent basis from claim 1.

In claim 19, the heterocyclic representing "dioxolanyl" and "dioxanyl" lacks antecedent basis from claim 1.

In claim 20, R^{6a} representing "diC₁₋₆alkyl-dioxolanyl" lacks antecedent basis from claim 1 and "diC₁₋₆alkyl-dioxolanyl" should be replaced by "di-C₁₋₆alkyl-dioxolanyl".

In claim 25, an "or" is needed before "carboxyl-C₁₋₆-alkyl".

In claim 26, an "or" is needed before "Het-C₁₋₆alkyl".

Art Unit: 1626

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Art Unit: 1626

Claims 1, 8-11, 13-20 and 25-30 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 and 9 of U.S. Patent No. 6,747,028; claims 1-4 and 7 of U.S. Patent No. 7,071,192 and claims 1, 2, 6 and 12-14 of U.S. Patent No. 7,173,034. Although the conflicting claims are not identical, they are not patentably distinct from each other because each of the above cited patents generically claim the instant claimed invention.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating a respiratory syncytial viral infection).

One skilled in the art would thus be motivated to prepare products embraced by the above cited patents to arrive at the instant claimed products with the

Art Unit: 1626

expectation of obtaining additional beneficial products which would be useful in treating, for example, a respiratory syncytial viral infection. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Claims 1, 8-11, 13-20 and 25-30 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2 and 13 of copending Application No. 11/332,557 . Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claimed invention is generically claimed in the copending application.

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814

Art Unit: 1626

(1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., treating a respiratory syncytial viral infection).

One skilled in the art would thus be motivated to prepare products embraced by the copending application to arrive at the instant claimed products with the expectation of obtaining additional beneficial products which would be useful in treating, for example, a respiratory syncytial viral infection. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Art Unit: 1626

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-11, 13-20 and 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lackey et al. {WO 02/092575} and Janssens et al. {WO 01/00611}.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicant claims benzimidazole compounds. Lackey et al. (see entire document; particularly Formula I, pages 7, 16-19, and 89-96; and especially Compounds 40 and 41 on page 28) and Janssens et al. (see entire document; particularly pages 2-4, 45 and 46; and especially Compound 286 on page 87) each teach

Art Unit: 1626

benzimidazole compounds that are structurally similar to the instant claimed compounds.

***Ascertainment of the difference between the prior art and the claims
(MPEP §2141.02)***

The difference between the compounds of the prior art and the compounds instantly claimed is that the instant claimed compounds are generically described in the prior art.

***Finding of prima facie obviousness--rational and motivation (MPEP
§2142-2413)***

The indiscriminate selection of "some" among "many" is *prima facie* obvious, In re Lemin, 141 USPQ 814 (1964). The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (e.g., an anti-viral).

One skilled in the art would thus be motivated to prepare products embraced by the prior art to arrive at the instant claimed products with the expectation of

Art Unit: 1626

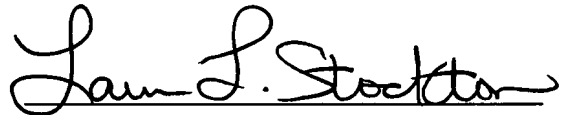
obtaining additional beneficial products which would be useful as an anti-viral. The instant claimed invention would have been suggested to one skilled in the art and therefore, the instant claimed invention would have been obvious to one skilled in the art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:15 am to 2:45 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1626

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

A handwritten signature in cursive script, reading "Laura L. Stockton". The signature is written in dark ink and is positioned above the printed name.

Laura L. Stockton, Ph.D.

Patent Examiner

Art Unit 1626, Group 1620

Technology Center 1600

October 9, 2007